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| 10/602,077 | 06/23/2003 | Stephen Suffin | CNSR-09275 | 1225 |

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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

| EXAMINER | |
|---|---|
| JONES, DAMERON LEVEST | |
| ART UNIT | PAPER NUMBER |
| 1618 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/602,077 | SUFFIN, STEPHEN | |
| | Examiner | Art Unit | |
| | D L. Jones | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *40-42,50-56 and 61-64* is/are pending in the application.

4a) Of the above claim(s) *61-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-42 and 50-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 1/21/09 wherein claims 1-39, 43-49, and 57-60 were canceled; claims 40-42 and 54-56 were amended; and claims 61-64 were added.

***Note***: Claims 40-42, 50-56, and 61-64 are pending.

**RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 1/21/09 to the rejection of claims 40-42 and 50-56 made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 9/19/08 and those set forth below.

***103 Rejection***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 40-42 and 50-56 under 35 U.S.C. 103(a) as being unpatentable over John (US Patent No. 6,067,467) is MAINTAINED for reasons of record in the office action mailed 9/19/08 and those set forth below.

In summary, Applicant asserts that the claims are not obvious over John because (a) the cited prior art indicates that a pre-anesthesia EEG measurement is not necessary, but optional. (b) John fails to teach EEG measurements from a drug and medication free patient. Applicant asserts that the measurements of John are taken when the patient is at least sedated, after the administration of at least one drug or medication. (c) Applicant asserts that John provides no motivation to successfully

create the instant invention. In particular, the system of John compares a first set of data from the patient before anesthesia is administered and a second set of data after the plane of anesthesia is attained. (d) Applicant asserts that the Examiner is improperly defining 'drug efficacy' in terms of whether the amount of a drug administered to a person is sufficient to elicit a desired response. (e) Applicant asserts that John does not teach clinical or therapeutic outcomes.

Applicant's arguments are non-persuasive for the reasons below and of record in the office action mailed 9/19/08. First, while pre-anesthesia measurements are not necessary, this does not mean that such measurement cannot or should not be taken. Also, for the record, in column 2, lines 49-51, it is disclosed that measurement of the patient's brain waves preferably begins a few minutes before the anesthetic is administered. In addition, in column 4, lines 42-44, it is disclosed that preferably, initial EEG measurements are taken while the patient is awake, ***before*** the anesthesia is administered. Thus, while the prior art does not *require* that EEG measurements, the step would be obvious since John discloses that EEG data may be taken before any drug/medication is administered. Furthermore, a skilled artisan would recognize that when initial data is taken before the administration of drugs/medication one may use the data for comparison purposes with that taken during and after a procedure.

Secondly, in regards to Applicant's assertion regarding how the Examiner is defining drug efficacy, the Examiner has not simply referred to the art which renders obvious Applicant's method steps. As a result, the position of the Examiner is that both the cited prior art and the instant invention may be used to determine medication

efficacy. In response to the assertion that the cited prior art does not teach clinical or therapeutic outcomes, the prior art was evaluated on whether or not it discloses or renders obvious the steps of the instant invention. Since the prior art renders obvious the steps of the instant invention, a rejection was made. Thus, if the prior art renders obvious the instant invention, then if Applicant's invention may be used for clinical or therapeutic purposes then it would be obvious that the prior art would have the same capability whether or not it specifically disclose so in the disclosure because both the prior art and instant invention disclose overlapping steps. Hence, the rejection is deemed proper.

**NEW GROUNDS OF REJECTIONS**

***112 First Paragraph Rejections***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 40-42 and 50-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the

world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the excluded paroxysmal events. In particular, paroxysmal events involve the sudden onset or recurrence of symptoms of a disease. However, the specification does not set forth the symptoms associated with the sudden onset or recurrence of diseases that are excluded from the instant invention. Furthermore, there are a multitude of diseases associated with the human body since any abnormal condition, affecting either the whole body or any of its parts. As a result, there are various classes of diseases including allogeneic, communicable, congenital, contagious, deficiency, endemic, functional, hereditary, infectious, local, mental, occupational, organic, periodic, social, systemic, and venereal. All of the symptoms that result in the onset or recurrence of the various diseases are not only unknown, but vary from subject to subject. Hence, based on the invention set forth what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based

on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed.

Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

***112 Second Paragraph Rejections***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-42 and 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because it is unclear what specific symptoms and diseases resulting from paroxysmal events are excluded from the instant invention.

**ELECTION BY ORIGINAL PRESENTATION**

7. Newly submitted claims 61-64 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. The newly submitted claims are directed for determining medication efficacy wherein step 'd' is directed to an outcome selected from Clinical Global Improvement score, a Hamilton-D score, or a Beck Depression score.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-64 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

April 23, 2009